

G. STEVEN GEIS, Ph.D., M.D.

PROFESSIONAL EXPERIENCE:

Pharmacia

Group Vice President: Arthritis, Cardiovascular and Oncology Clinical Development (March 2001 – July 2002)

While maintaining responsibility for the arthritis therapeutic area, assumed leadership for the clinical cardiovascular and oncology teams in March, 2001 and April, 2002, respectively. Establishing a functional global oncology team required integrating clinical sites in Italy and throughout the US. Achievements included the successful, on-target submission of an NDA for a specific-aldosterone receptor antagonist (eplerenone) in January, 2002. Oncology projects continued according to strategy with successful enrollment for two clinical trials designed to assess the role of celecoxib in spontaneous adenomatous polyposis. For arthritis, clinical trials were conducted to garner additional indications for Celebrex®, Bextra® and Dynastat® and the development strategy was completed and a plan implemented for a disease modifying agent for rheumatoid arthritis. Also, assumed responsibility for leading a company-wide, multidisciplinary strategy team for establishing and implementing development strategies for new compounds for arthritis, inflammation and pain.

Searle/Monsanto

Vice President: Arthritis Clinical Development (August 1998 – March 2001)

Promoted to this position in 1998 after submitting the celecoxib NDA and, after FDA agreed to an expedited review. Charged with leading an R&D cross-functional team to ensure a successful Advisory Committee Meeting and served as a participant on a label negotiating team while continuing to support global approvals. Also led the Phase IIIb and IV clinical development of celecoxib for arthritis, CNS and oncology claims/indications with budget responsibilities approximating _____ per year. Forged cross-functional relationships between the commercial and scientific teams both within and outside the company. An extraordinarily successful Advisory Committee Meeting was realized and successful label negotiations were completed by end 1998 which effectively described the data that differentiated celecoxib from NSAIDs. A team that included representatives from the pharmaceutical partner, Pfizer, was the operational model for the successful performance at the Advisory Committee Meeting. Also, charged with the development of all other compounds for arthritis, inflammation and pain, including valdecoxitib (Bextra®), parecoxib (Dynastat®) and a selective iNOS inhibitor. During the 13-month period of January 2000 through January 2001, NDAs were submitted for parecoxib and valdecoxitib while two sNDAs were submitted for additional claims for celecoxib. To accomplish these aggressive goals, created a High Performance Arthritis Clinical Team that was expanded by 35 highly talented members over a 5 month period.

Executive Director: High Performance Celecoxib Clinical Team (July 1996 - August 1998)

Requested by management to lead a High Performance Celecoxib Clinical Team to ensure the completion of US and ex-US dossiers by June, 1998. Responsibilities also included serving as primary clinical contact for the Searle Arthritis Franchise and the Pfizer regulatory and commercial partnership. All goals were achieved on-target and with high quality. The celecoxib dossier included 51 clinical trials, approximately 13,000 study participants and over 5,000 patient years of drug exposure. Time from first-in-humans to NDA submission was 36 months. A team-based model, including internal cross-functional partnerships, the Pfizer partnership and partnerships with external consultants and clinical research organizations (CROs), was the operational basis for success. Budget responsibilities were approximately _____ per year.

Executive Director: Arthritis Clinical Development (April 1995 - July 1996)

With a reorganization of the clinical department, was requested to direct global clinical research for compounds designed to treat the signs and symptoms of rheumatoid arthritis, osteoarthritis and for the management of pain. Arthrotec®, a fixed combination product of misoprostol and diclofenac, which had been developed internationally, was submitted to FDA, approved for marketing and successfully launched in the US. The introduction of Arthrotec®

was considered the second most successful US launch for 1998 and first-year sales exceeded \$1 billion. Oxaprozin potassium, the salt of Daypro® was developed and submitted in the US for approval for the management of pain. The development strategies for celecoxib, a backup compound and the second generation to celecoxib were completed. In addition, served as leader of the Searle Arthritis/Inflammation Program Team - a cross-functional team with representatives from R&D and commercial for establishing development strategies consistent with commercial goals.

Executive Director: Arthritis, Gastroenterology and Cardiovascular (July 1992 - April 1995)

Responsible for clinical development of compounds for arthritis, gastrointestinal and cardiovascular conditions. Clinical development plans were designed and implemented for: a Class I anti-arrhythmic agent that entered Phase III with a design developed in conjunction with FDA, an anti-asthmatic, a leukotriene B4 antagonist for psoriasis and ulcerative colitis, an angiotensin II-receptor antagonist for hypertension, and a glycoprotein IIb/IIIa-antagonist for prevention of thrombosis. Led the conduct of a significant Phase II clinical trial with spironalactone for control of congestive heart failure that provided the basis for development of a new antialdosterone compound. Led the completion and successful publication of the MUCOSA trial, an 8,000 patient study that demonstrated the efficacy of Cytotec® in preventing potentially fatal ulcer complications of NSAIDs.

Senior Director: Gastroenterology (June 1988 - July 1992)

Responsible for worldwide development of compounds related to gastrointestinal and arthritis conditions. Led the team that established the clinical development plan for Arthrotec® approval outside the US. The plan was successfully implemented, the dossier completed and regulatory approval was achieved in European, Canada and Latin American. Served as primary presenter at the CPMP approval hearing.

Director: Gastroenterology (August 1987 - May 1988)

Responsible for worldwide development of compounds for gastroenterology. Activities resulted in completion of a core dossier for Cytotec® an exogenous prostaglandin which was approved on a worldwide basis for the prevention of NSAID-induced upper GI ulceration. Presented the safety review at the Advisory Committee Meeting.

Associate Director (June 1985 - August 1987)

Responsible for designing and monitoring clinical trials for gastrointestinal compounds. Multicenter trials were conducted for establishing the GI protective effects of misoprostol against NSAID damage. These trials became the basis of the successful worldwide approval of Cytotec® for the prevention of NSAID GI ulceration.

ACADEMIC BACKGROUND:

<u>Institution</u>	<u>Period</u>	<u>Degree</u>
St. Louis University School of Medicine St. Louis, Missouri	1979-1983	M.D.
Loyola University of Chicago Stritch School of Medicine Maywood, Illinois	1974-1979	Ph.D./Physiology
Dissertation: Central organization and spinal control of the cardiac vagus		
St. Louis University St. Louis, Missouri	1969-1973	B.A./Chemistry

PUBLICATIONS: see attached

AWARDS:

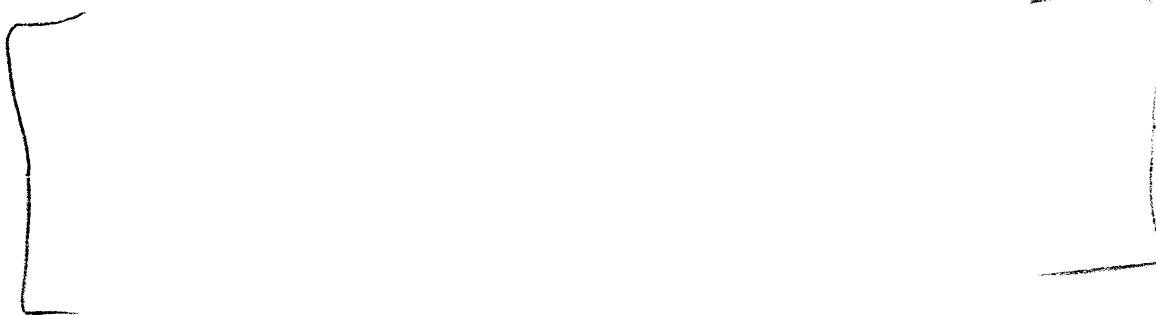
Co-recipient of the 1999 Edgar M. Queeny Award from Monsanto for the development of Celebrex®, the first specific COX-2 inhibitor approved by the FDA, that was marketed for medical use in January, 1999. The drug was an extraordinary commercial success. More new prescriptions _____ were filled in its first year on the market than the next two leading blockbusters combined during the same post-launch period. The Edgar M. Queeny Award was presented annually by the Monsanto Corporation in recognition for the development of unique, proprietary technology that resulted in commercial success.

BOARD MEMBERSHIP:

Kindle International Research (October, 2002 – present)

Serving on Board of Directors for the global, publicly held clinical research organization (CRO) founded to provide R&D, regulatory and commercial expertise for the biotech and pharmaceutical industry.

CIVIC CONTRIBUTIONS:



**APPEARS THIS WAY
ON ORIGINAL**

PUBLICATIONS

Ph.D. Thesis

GEIS G.S. Central Organization of the Cardiac Vagus. Ph.D. Dissertation. Loyola University. Chicago, Illinois. 1979.

Manuscripts

1. McCaffrey T.V., Wurster R.D., GEIS G.S. Reflex control of sweating by skin temperature in man. Seventh International Biometeorological Congress. College Park, Maryland, U.S.A. August 17-23, 1975.
2. McCaffrey T.V., GEIS G.S., Chung J.M., Wurster R.D. Effect of isolated head heating and cooling on sweating in man. Aviat Space Environ Med 1975;46(11):1353-1357.
3. GEIS G.S., Barratt G.E., Wurster R.D. Role of the descending pressor pathway in the conscious and pento-barbital-anesthetized dog. Am J Physiol 1978;234(2):H152-H156.
4. GEIS G.S., Wurster R.D. Localization of an ascending chronotropic pathway. Fed Proc 1978;37(3):702.
5. McCaffrey T.V., Wurster R.D., Jacobs H. K., Euler D. E., GEIS G.S. Role of skin temperature in the control of sweating. Am J Physiol 1979;47(3):591-597.
6. GEIS G.S., Wurster R.D. Horseradish peroxidase localization of cardiac vagal preganglionic somata. Brain Res 1980;182:19-30.
7. GEIS G.S., Wurster R.D. Cardiac responses during stimulation of the dorsal motor nucleus and nucleus ambiguus in the cat. Circ Res 1980;46:606-611.
8. GEIS G.S., Kozelka J. W., Wurster R.D. Organization and reflex control of vagal cardiometer neurons. J Auton Nerv Syst 1981;3:437-450.
9. GEIS G.S., Wurster R.D. Localization of ascending inotropic and chronotropic pathways in the cat. Circ Res 1981;49:711-717.
10. GEIS G.S., Randall W.C., Wurster R.D. Localization of canine vagal preganglionic somata to the atrioventricular node. Fed Proc 1985;44(3):469.
11. Ardell J.L., GEIS G.S., Randall W.C., Wurster R.D. Selective innervation of sinoatrial and atrioventricular nodes in the canine heart. J Physiol 1986;371:66.
12. GEIS G.S., Ardell J.L. Selective vagal innervation of the heart. Ann Clin Lab Sci 1986;16(3):198-208.
13. Randall W.C., Milosavljevic M., Wurster R.D., GEIS G.S., Ardell J.L. Selective vagal innervation of the heart. Ann Clin Lab Sci 1986;16(3):198-208.
14. Randall W.C., Tasch D., GEIS G.S., Wurster R.D., Ardell J.E. Brainstem localization of somata mediating sinoatrial and/or atrioventricular function in the dog.
15. Randall W.C., Tasch D., GEIS G.S., Wurster R.D., Ardell J.E. Brainstem localization of somata mediating sinoatrial and/or atrioventricular function in the dog. Fed Proc 1986;45(4):771.
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17. Lanza F.L., Fakouhi D., Rubin A., Davis R.E., Rack M.F., Nissen C.H., GEIS G.S. A double-blind placebo controlled comparison of the efficacy and safety of 50 mcg, 100 mcg and 200 mcg of misoprostol QID in the prevention of ibuprofen induced gastric and duodenal mucosal lesions and symptoms. Am J Gastroenterol 1989;84(6):633-636.
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21. Martin L.F., Booth F.V., Reines D., Deysach L.G., Kochman R.L., Erhardt L.J., GEIS G.S. Stress ulcers and organ failure in intubated patients in surgical intensive care units. Ann Surg 1992;215:332-337.
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24. GEIS G.S. Arthrotec®: A therapeutic option in the management of arthritis. Eur J Rheumatol Inflamm 1993; 13(1):25-32.
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59. Robinson J., Woods E., Hubbard R.C., Yu S., GEIS G.S. Efficacy and safety of celecoxib for the treatment of osteoarthritis of the hip. [Submitted to the J Clin Rheum]
60. Tindall E.A., Sharp J.T., Burr A.M., Katz T.Z., Zhao W.W., Lefkowith J.B., GEIS G.S. Celecoxib is associated with significant ACR responses and may modify disease progression in rheumatoid arthritis. [In preparation for submission to J Clin Pharmacol]
61. Tindall E.A., Sharp J.T., Burr A.M., Katz T.Z., Zhao W.W., Lefkowith J.B., GEIS G.S. Long-term celecoxib therapy does not affect radiographic progression of OA of the hip or knee. [In preparation for submission to J Clin Rheum]

Journal Supplements

1. GEIS G.S., Stead H., Wallemark C., Nicholson P.A. Prevalence of mucosal lesions in the stomach and duodenum due to chronic use of NSAID in patients with rheumatoid arthritis or osteoarthritis, an interim report on prevention by misoprostol of diclofenac associated lesions. *J Rheumatol* 1991;18(Suppl 28):11-14.
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- Congress of Rheumatology, Budapest, Hungary. [Concluding Discussion] Scand J Rheumatol 1992;(Suppl 96):55-56.
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 4. GEIS G.S. Antiinflammatory efficacy versus gastrointestinal safety - a dilemma resolved. Proceedings from a Scientific Symposium, 2 July 1991 at the 12th European Congress of Rheumatology, Budapest, Hungary. [Comment] Scand J Rheumatol 1992;(Suppl 96):57.
 5. GEIS G.S. Commentary. Scand J Rheumatol 1992;(Suppl 96):57.
 6. GEIS G.S. Update on clinical developments with celecoxib, a new specific COX-2 inhibitor: what can we expect? J Rheumatol 1999;26(Suppl 56):31-36.
 7. GEIS G.S. Update on clinical developments with celecoxib, a new specific COX-2 inhibitor: what can we expect? Scand J Rheumatol 1999;28(Suppl 109):31-37.

Abstracts

1. GEIS G.S., Wurster R.D. The role of the descending spinal sympathetic pathway in the unanesthetized dog. Fed Proc 1976;35(3):324.
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3. GEIS G.S., Wurster R.D. Localization of an ascending chronotropic pathway. Fed Proc 1978;37(3):702.
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6. GEIS G.S., Wurster R.D. Localization of an ascending inotropic pathway. Physiologist 1979;22:43.
7. GEIS G.S., Wurster R.D. Central physiological organization of the cardiac vagus. Neuroscience Abstracts 1979;5:42.
8. Wurster R.D., GEIS G.S. Cardiac autonomic preganglionic innervation. Proceedings of the International Union of Physiological Sciences 1981.
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11. Lanza F.L., GEIS G.S., Kochman R.L. A comparison of misoprostol 400 mcg controlled release BID (MCR) and misoprostol 200 mcg QID immediate release (MIR) with placebo in preventing aspirin-induced upper GI lesions. Gastroenterology 1990;98(5 Part 2):A75.
12. Lanza F.L., GEIS G.S., Kochman R.L. Misoprostol in preventing aspirin-induced upper lesions: comparison of BID and QID dosing to controlled release. Gastroenterology 1990;98(5 Part 2):A76.
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15. GEIS G.S., Erhardt L.J., Stead H. Prevention of diclofenac-induced gastroduodenal mucosal lesions by misoprostol: a multinational, placebo controlled, parallel group study. Hungarian Rheumatol 1991;(Suppl 32):366.
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17. Stead H., GEIS G.S. Diclofenac/misoprostol fixed combination in patients with osteo-arthritis. Hungarian Rheumatol 1991;(Suppl 32):367.
18. Woods E.M., GEIS G.S., Onkelinx C. Comparison of diclofenac/misoprostol and diclofenac in rheumatoid arthritis. Hungarian Rheumatol 1991;(Suppl 32):367.
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